A Scalable Quality Management System (QMS) Supporting Life Sciences

By: Trupti Shinde

OBJECTIVE:

This presentation provides Project Managers in software companies supporting Life Sciences a step by step guideline to implement a scalable Quality Management System (QMS).

Software Companies that Support Life Sciences

Software development companies develop software applications to support business processes for pharma and MedTech. Software solutions developed can be both GxP or non-GxP.

- GxP Software Systems: Directly impact product quality, patient safety, or regulatory compliance. E.g. Clinical Trial Management Systems (CTMS)

- Non-GxP Software Systems: Supportive in nature, not directly tied to product quality or patient safety. E.g. HR systems, collaboration tools (Teams, Slack), project management tools (Smartsheet, MS Project)

Functional Areas in Life Sciences

Functional Area:	Key Project Management Interface:
R&D	Discovery milestones, innovation timelines
Clinical Operations	Trial timelines, CRO/vendor oversight
Regulatory Affairs	Submission deadlines, documentation coordination
Quality/Compliance	Audits, SOPs, validation, training
Manufacturing/CMC	Tech transfer, scale-up, facility readiness
Supply Chain	Vendor timelines, materials tracking
IT / Digital Systems	Software validation, QMS implementation
Medical Affairs	Scientific content planning, MedInfo tools
Commercial / Marketing	Launch planning, promotional approvals
Finance & Legal	Budgeting, contracts, legal risk review

Importance Of QMS For Software Companies Supporting Life Sciences

- Product meets higher quality & customer satisfaction
- Ensures software is safe, effective, and compliant
- Required for working with pharmaceutical & MedTech clients
- Aligns with regulatory expectations such as Food and Drug Administration(FDA), European Medicine Agency (EMA).

Quality Management System

- A formalized system of policies, processes, and procedures that an organization uses to ensure its products or services consistently meet customer and regulatory requirements.
- System for tracking deviations analyze data, and integrated workflows to manage the full deviation lifecycle.

Key Standards and Frameworks

- 21 CFR Part 11: 21 CFR Part 11 applies to GxP-regulated software systems includes Audit trails, e-signatures, validation.
- ISO 13485: It is a quality management standard used specifically by the medical device industry.
- GAMP 5 & CSA/CSV: GAMP 5 is a globally recognized framework for risk-based validation, while CSA/CSV is the FDA's initiative to ensure patient safety and product quality.
- ISO 9001: focuses on process consistency, customer satisfaction, and continuous improvement.
- ISO 27001: An internationally recognized standard for information security management systems (ISMS), providing a framework for organizations to manage the confidentiality, integrity, and availability of their data.

CSV (Computer System Validation) And CSA (Computer Software Assurance) Comparison

CSV (Computer System Validation)

- A documented process of ensuring that a computer system is suitable for use.
- Ensure computer system does exactly what it was designed to do in a consistent and reproducible manner.

CSA (Computer Software Assurance)

- A risk-based approach to ensure that software is fit for its intended use.
- Risk assessment is driven by the potential impact the software function has on patient safety, product quality, and data integrity.

QMS-Implementation Steps

Business Process Optimization

I. Develop Core SOPs
II. Identify workflows for QMS Process
III. Conduct Resource Training
IV. Establish Compliance Controls

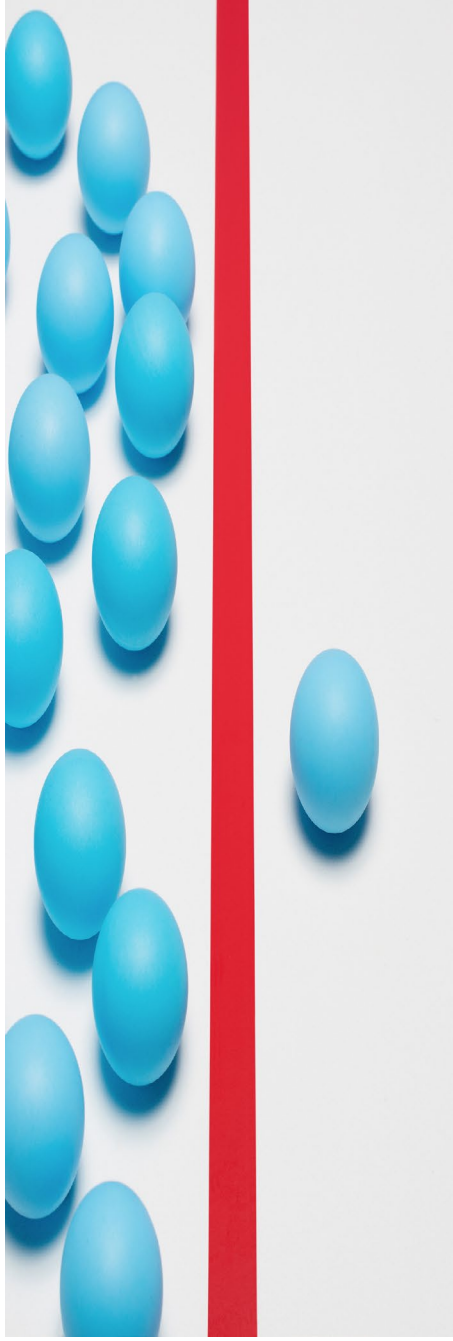
QMS Software Rollout Plan

I. Develop CAPA module
II. Audit Trail Enhancements
III. Gather Product Quality Metrics
IV. Data Analytics

Case Study: Implementing QMS For A Medical Communications Software Company

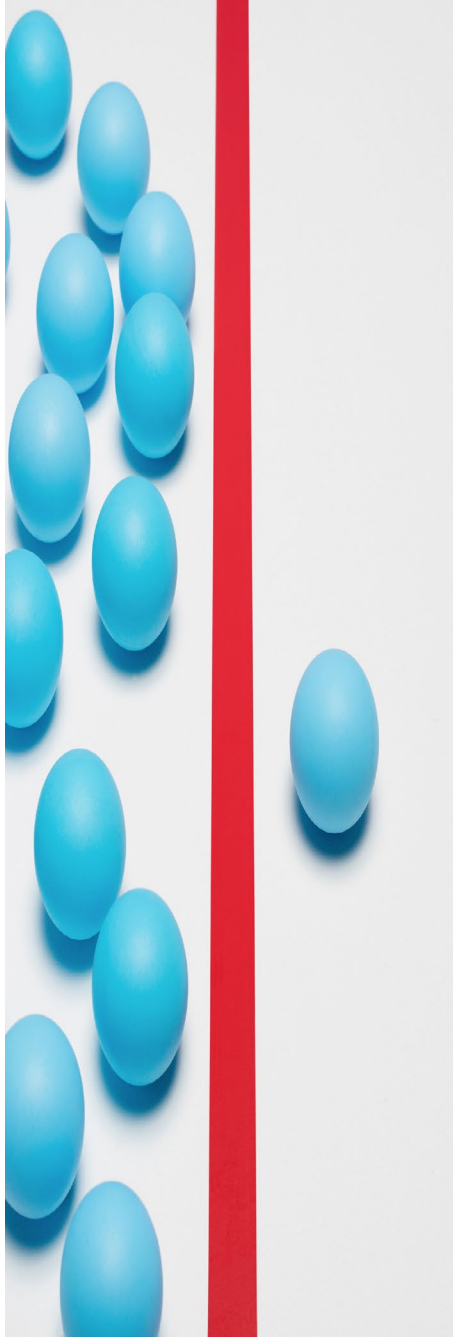
Problem Statement

A software company providing SaaS solution (non GxP) to pharmaceutical companies for medical affairs and medical communications faces challenges in tracking and resolving quality issues efficiently, while ensuring compliance with business requirements.



Solution:

Implement a Quality Management System(QMS) to resolve Quality complaints by tracking and resolving quality issues efficiently, while ensuring compliance with business requirements.



Quality Management System-Purpose

- Audit Readiness and Vendor Qualification
  - QMS supports vendor audits & health authority inspections
- Product and Service Quality
  - Facilitates root cause analysis and impact assessment
  - Manages defect tracking, change control, and Corrective and Preventive action (CAPA)
- Customer Satisfaction
  - Driving continuous improvement through structured feedback loops to exceed expectations

Key Tasks For Successful QMS Program

I. Establishing Quality Management System and Process
II. Build Organization SOP & Policy Development Process
III. Implementation of Training Management System
IV. Development of Compliance & Risk Management Framework
V. Continuous Improvement and Audit Readiness

Establishing Quality Management System

Task Objective:

Identify and implement a QMS software solution that supports CAPA, non-conformance, issue management, provides document management support for audit

Key Steps:

- Assess business needs and select QMS software
- Configure workflows to identify root causes, assess impact, and determine CAPA or non-conformance actions.
- Conduct CSV validation to ensure compliance.
- Train users and roll out in phases.

Project Management Strategies:

- **Stakeholder Engagement:** Involve Quality, IT, and Compliance teams.
- **Planning & Execution:** Use an incremental Agile approach for implementation.
- **Risk Mitigation:** Conduct a pilot rollout before full deployment.
- **KPIs:** System adoption rates, defect resolution efficiency, compliance audit readiness.

Development of Compliance & Risk Management Framework

Task Objective:

Develop a framework for managing regulatory compliance and risks in software development for medical communications.

Key Steps:

- Identify compliance gaps in processes and software systems.
- Develop risk assessment methodologies based on FDA recommendations.(CSA)
- Implement audit tracking and reporting dashboards.
- Conduct regular risk assessments and compliance checks.

Project Management Strategies:

- **Stakeholder Engagement:** Involve risk and compliance teams.
- **Execution Strategy:** Implement GAMP 5 best practices for system validation.
- **Risk Mitigation:** Establish an issue-tracking mechanism for regulatory gaps.
- **KPIs:** Number of audit findings, risk mitigation effectiveness, CAPA closure rates.

Develop Organization SOP Review Approval Process

Task Objective:

Ensure all processes within the QMS framework are documented, reviewed, and compliant with CSV (Computer System Validation) and CSA (Computer Software Assurance).

Key Steps:

- Identify gaps in existing SOPs.
- Revise and draft new policies aligning with GxP regulations.
- Engage cross-functional teams for reviews and approvals.
- Implement version control mechanisms.

Project Management Strategies:

- **Stakeholder Engagement:** Conduct workshops with compliance, IT, and quality teams.
- **Scheduling & Execution:** Define milestones for document drafting, review, and approval.
- **Risk Mitigation:** Use a change control process to track SOP updates.
- **KPI Tracking:** Monitor SOP review cycle time, adherence to regulatory updates.

Implementation of Training Management System

Task Objective:

Ensure all employees understand and comply with QMS policies, SOPs, and regulatory requirements.

Key Steps:

- Implement an LMS (Learning Management System) to track and assign training.
- Develop role-based training programs for different departments.
- Conduct periodic compliance training refreshers.
- Track employee training completion and effectiveness.

Project Management Strategies:

- **Communication Strategy:** Regular training updates, leadership alignment
- **Execution:** Use Agile methodology to phase out training in sprints.
- **Risk Mitigation:** Implement audit trails to track training records.
- **KPIs:** Training completion rates, audit compliance scores.

Continuous Improvement And Audit Readiness

Task Objective:

Ensure the QMS remains effective, up to date, and audit-ready Continuously.

Key Steps:

- Conduct internal audits and gap analysis.
- Implement CAPA improvements based on audit findings.
- Monitor system performance metrics.
- Continuously update the QMS based on regulatory changes.

Project Management Strategies:

- **Planning & Execution:** Establish an annual audit plan.
- **Stakeholder Engagement:** Involve leadership in continuous improvement initiatives.
- **Risk Mitigation:** Maintain a dynamic risk register.
- **KPIs:** Number of non-conformances detected, effectiveness of CAPA actions, audit scores.

Key Takeaways

Building a QMS program requires a structured program management approach.

Through incremental projects, the company ensured:

- Regulatory compliance (CSV, CSA, GxP regulations)
- Operational efficiency through structured training and SOPs
- Scalable software solutions to manage CAPA and non-conformances
- Risk mitigation through continuous monitoring and audit readiness

Thank You

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